

PRIDE DRUGS & PHARMA (P) LTD- BILESHWARPURA


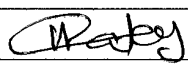
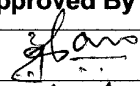
Department QUALITY CONTROL	Title: FINISHED PRODUCTS SPECIFICATION	Page : 1 of 4
	Specification No: SP-FG-FMT-020/05	Effective Date : 24/12/24
	NAME OF MATERIAL: FERRIC MALTOL FOOD GRADE	Supersedes : SP-FG-FMT-020/04

1.0 GENERAL INFORMATION:

Chemical name/Synonym	1] Iron (3+) tris (2-methyl-4-oxo-4H-pyran-3-olate) 2] Iron(III)Maltol
Molecular Formula	C ₁₈ H ₁₅ FeO ₉
Molecular Weight	431.15
Sampling Quantity	15 g
Reference	In-house + IP
Retesting Period	24 Months

2.0 SPECIFICATION :

Sr. No.	Test	Specification	Method No
01	*Description	Light brown to reddish brown powder.	FG-FMT-020/M01/01
02	Identification by Infrared spectroscopy	The infrared spectrum of the test preparation should exhibit maxima at the characteristic wavenumbers 1565, 1501, 1274 and 1203 cm ⁻¹ (± 10 cm ⁻¹).	FG-FMT-020/M02/01
03	pH (1.0 % solution in water)	Between 5 and 8	FG-FMT-020/M03/01
04	Water Content By KF	Not more than 2.0% w/w	FG-FMT-020/M04/01
05	*Loss on drying (105 °C for 3 hrs.)	Not more than 2.0 % w/w	FG-FMT-020/M05/01
06	*Iron content by UV (On dried basis)	Between 12% w/w to 14% w/w	FG-FMT-020/M06/01
07	*Maltol content by HPLC (On dried basis)	Between 86% w/w to 88% w/w	FG-FMT-020/M07/01
08	*Related substances by HPLC: Citric acid Any unspecified impurity Total impurities	Not more than 0.15% Not more than 0.10% Not more than 1.0%	FG-FMT-020/M08/02

Signature	Prepared By 	Checked By 	Approved By 
Date	24/12/24	24/12/24	24/12/24
Name	Tushar Patel	Vijay Patel	Amit Soni

MASTER COPY

PRIDE DRUGS & PHARMA (P) LTD- BILESHWARPURA


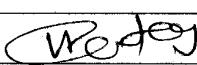
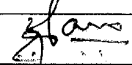
Department QUALITY CONTROL	Title: FINISHED PRODUCTS SPECIFICATION	Page : 2 of 4
	Specification No: SP-FG-FMT-020/05	Effective Date : 24/12/24
	Supersedes : SP-FG-FMT-020/04	
NAME OF MATERIAL: FERRIC MALTOL FOOD GRADE		

Sr. No.	Test	Specification	Method No
09	*Iron (II) content by titrimetry	Not more than 0.15 % w/w	FG-FMT-020/M09/01
10	*X-ray Diffraction	X-ray diffractogram of the test sample should show polymorphic Form-II characteristic 2θ values at 8.3°, 9.5°, 11.8°, 14.5°, 15.5°, 19.2°, 19.8°, 21.1° and 23.0° ($\pm 0.2^\circ$).	FG-FMT-020/M10/02
11	Microbial Enumeration Test :		
	(A) Total Aerobic Microbial Count (TAMC)	NMT 1000 cfu/g.	FG-FMT-020/M11/01
	(B) Total Combined Yeast and Mold Count (TYMC)	NMT 100 cfu/g.	

Remark: The '*' indicate retest and Stability test Parameter.

3.0 WARNINGS:

Storage	Preserve in well-closed container at 20°C to 25°C (68°F to 77°F), excursions allowed between 15°C and 30°C (59°F and 86°F).
Packing	Packed in 3 bag system (inner transparent/Milky white LDPE bag under nitrogen followed by black LDPE bag and outer Poly laminated aluminum bag). Then placed in HDPE container and closed.
Sample Handling & Disposal	Refer MSDS.

Signature	Prepared By	Checked By	Approved By
			
Date	24/12/24	24/12/24	24/12/24
Name	Tushar Patel	Vijay Patel	Amit Soni

MASTER COPY